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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,071	12/18/2001	Kurt R. Linberg	P-8558.04	3669

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EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,071	LINBERG, KURT R.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-29 and 59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-29 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 16-18, 23 and 59 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Knapp et al. (Pat. No. 5,300,120).

Knapp et al. disclose at least one medical component (note col. 5, lines 3-12), a programmer 34/36 capable of identifying the medical component implanted, a remote expert data center positioned globally at a distal location relative to the programmer (see col. 2, lines 29-37 and col. 4, lines 1-7), an interface between the programmer and the remote expert data center (e.g., the telephone and modem discussed in columns 2 and 4), and an inventory control module 38 (or equivalent data bank control computer/module at the remote site) in data communication with the remote expert data center for receiving information identifying the medical component implanted in the patient and for updating an inventory module (data bank) regarding inventory of the medical component implanted in the patient as required by the Safe Medical Device Act of 1990 (note col. 1, lines 14-37 and claim 1). Although Knapp et al. doesn't explicitly refer to an implanted medical device system (the examiner considers a collection of implanted components to collectively constitute an implanted medical device system) used in conjunction with the at least one medical component, as it is well-established

that a single patient may need more than one component simply depending on his/her condition, those artisans of ordinary skill in the art would have seen the provision of a system of components as obvious. In the case of breast implants (note col. 1, line 12), two implants would normally be required –each with a transponder. The examiner further considers the programmer of Knapp et al. capable of identifying each medical component by virtue of the fact that each transponder may be encoded with one of about a trillion different code combinations (col. 3, lines 42-44) to allow for a unique identification tag signal (note claim 1), and thus allow for an update of the inventory of each component.

Regarding the use of a programmer, the examiner considers the decoder/controller 36 to constitute such structure in the absence of any means-plus-function language. In any event, the examiner takes Official Notice that the use of programmers in conjunction with pacemakers, defibrillators, or other controllable medical devices as a means to receive transmitted data is old and well-known. To therefore utilize a programmer already known and specifically designed to receive transmitted information for receiving the transponder signal discussed by Knapp et al., would have been considered obvious by those of ordinary skill in the implantable medical device field.

Regarding claims 17 and 18, note col. 1, line 12.

Concerning claim 59, comments paralleling those made above in the rejection of claim 16 apply here as well.

Claim Rejections - 35 USC § 103

4. Claims 19-22 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knapp et al..

Regarding the use of a defibrillator (claim 19), Knapp et al. disclose that a wide variety of implants may be employed in the invention, with the scope of the invention being broad enough to encompass any implant presently known to the inventors (col. 5, lines 3-12). It is axiomatic that implantable defibrillators are widely known to artisans of ordinary skill in the medical field. To employ an implantable defibrillator would have therefore been considered blatantly obvious.

Likewise for claim 20, since leads are known implants in medical systems and in wide use, those of ordinary skill in the art would have seen the obviousness of utilizing the system of Knapp et al. to identify any implanted leads.

Regarding claims 21, 22, 24-26, note col. 2, lines 29-32. Clearly any suitable form of communication link in known use and associated with data transfer such as LAN, the Internet, satellite communications, GPS, etc., would have been considered a matter of obvious design by the network engineer. These systems are well-known in conjunction with computerized data transfer, with the number of links and the type of links employed being a matter of obvious design and dictated by the communication systems available for the particular location involved. A combination of links may be required, for example, to access the centralized site in remote areas absent reliable telephone communication lines.

Regarding claim 27, those of ordinary skill in the art would have seen the particular coding method employed to identify the component as an obvious matter of design based upon what technique was found to be most suitable for the situation at hand and the available decoder equipment in use.

Concerning claims 28 and 29, although Knapp et al. do not explicitly discuss identifying the serial number and/or model number, the Safe Device Medical Act of 1990 discussed in col. 1 of the Knapp et al. reference does require such information. To design the system to abide by this Act would have therefore been considered obvious by any ethical medical device artisan.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

KJS
December 9, 2003

KENNEDY SCHAETZLE
PRIMARY EXAMINER